

EBOLA VIRUS DISEASE TESTING
Revised Testing and Shipping Instructions
November 10, 2014

Important: Contact your local Health Department Epidemiology representative for all suspect Ebola virus cases.

I. Key Points:

- Department of Transportation (DOT) classifies SUSPECT Ebola specimens as “Risk Group 4” agents.
 - Risk Group 4 (RG4) classification applies to those agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.
 - Biosafety Level 4 (BSL4) classification applies to a combination of laboratory practices/techniques, safety equipment and laboratory facilities that provide a level of containment adequate to work with dangerous and exotic agents that pose a high risk of life-threatening disease. This includes diseases transmitted via aerosol transmission and diseases for which there is no available vaccine or therapy available.
- DOT requires that “contracted” couriers only transport packages containing Risk Group 4 suspected or confirmed agents that are prepared by Category A certified individuals.
- Category A packages must include DOT-approved labeling, packaging materials and shipper’s declaration.
- DCLS is providing Category A/Risk Group 4 collection/shipping kits (**See Section VII**) to all area Health Districts for Ebola virus testing. These kits will be provided to facilities as needed.
- DCLS can also provide a kit directly to a facility if one cannot be obtained from the area Health District. The kit will only be issued once a suspect case has been approved for testing by VDH/CDC.
- **Please communicate to DCLS if your facility does not have staff certified to package and ship Category A specimens.**
- DCLS is working to find alternative options for those facilities that are not certified to package and ship Category A specimens.
- Again, a courier cannot be deployed to retrieve a Risk Group 4 specimen that has not been packaged properly by a person certified in packaging Category A specimens using defined DOT requirements.

II. PCR Testing (**Update as of 10/21/14**)**

- DCLS will perform real-time PCR testing for Ebola virus once testing has been approved by VDH and CDC.
****NOTE: Testing will not be performed without prior consultation with VDH and CDC.**
- Ebola virus can be detected in blood only after onset of symptoms, most notably fever; however, it may take up to 3 days post-onset of symptoms for the virus to reach detectable levels.
- The real-time PCR assay detects the presence of RNA for the Ebola Zaire virus.
 - **Negative test results** are considered final test results.
 - Confirmatory testing at CDC is **NO LONGER** required.
 - If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola virus infection.
 - If Lassa Fever is being considered as a cause of illness, DCLS will refer a blood specimen to CDC for Lassa Fever testing.
 - **Positive test results** will be confirmed at CDC. DCLS will refer a blood specimen to CDC for confirmatory testing.

III. Specimen Collection

- Collect **2 lavender top** blood tubes (plastic tubes only) containing **whole blood** preserved with EDTA (**minimum volume of 4mL each**).
 - One specimen will be tested at DCLS.
 - DCLS will forward the second whole blood tube to CDC for confirmatory testing and additional viral testing.
- Collect blood in **plastic** tubes only. **Do not collect in glass tubes.**
- **Do not centrifuge specimens.**
- Specimens should be stored and shipped at 4°C.

IV. Submission Forms

- Complete and submit the DCLS Clinical Microbiology/Virology Request Form.
- Provide all patient information, including full address and medical history.
- Write “Ebola virus” as the disease suspected in the “Patient Medical History” section.
- Complete Shipper’s Declaration Form (must have red border)
NOTE: The Shipper’s Declaration form must to be completed by a certified Category A shipper using compliance checking software. Form can be prepared at www.saftypak.com, individual registration is required.
- Place 3 copies (**two must be printed in color**) of the printed shippers declaration in the plastic sleeve that is attached to the outermost insulated shipper.

V. Specimen Packaging

- Category A/Risk Group 4 collection/transport kits will be provided to all Health Districts Specimens (blood tubes) should be packaged following the basic triple packaging system (**see diagram #1 below**):
 - Primary “shipping” receptacle (sealable specimen bag) wrapped with absorbent material
 - Secondary “shipping” receptacle (watertight, leak-proof, and puncture proof container)
 - Tertiary “shipping” receptacle (rigid outer shipping package)
- If multiple primary receptacles will be placed in a single secondary receptacle, they must be individually wrapped or separated to prevent contact between them.
- Submission form should be included in the package **outside** of the secondary receptacle.
- The shipping receptacle should have the appropriate DOT-approved labeling required for Category A packages (**see diagram #2 below**)

Diagram #1: Triple Packaging System for Category A Packages

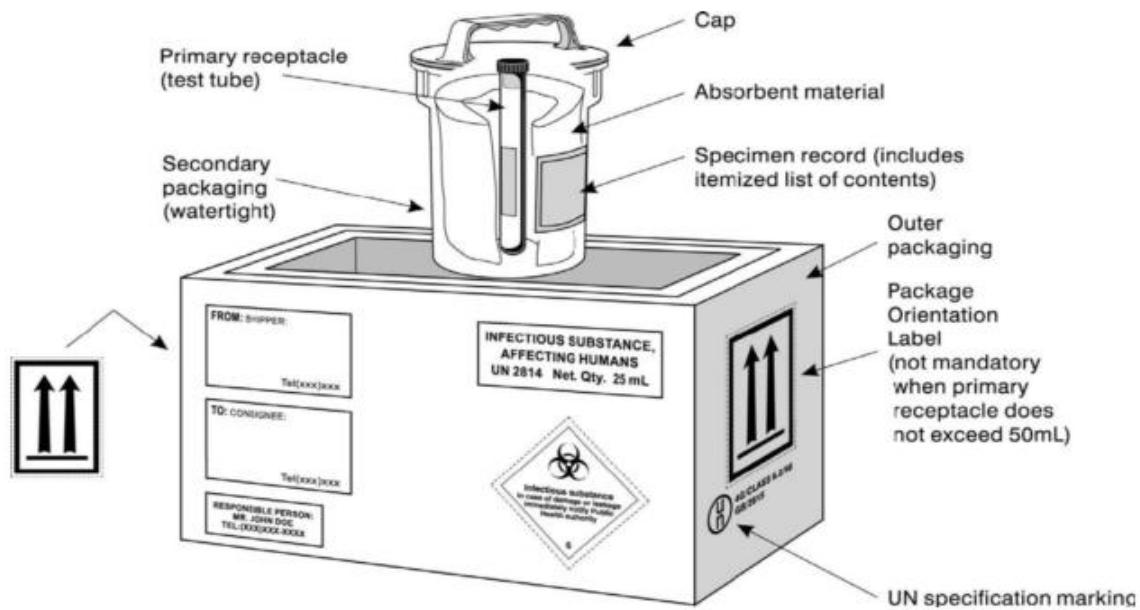


Diagram #2: DOT-Approved Category A Labeling



Infectious Substance,
Affecting Humans
UN2814

VI. Specimen Transport

- DCLS **must** be contacted to make arrangements for specimen transport after VDH/CDC has approved testing.
- DCLS bonded courier will pick-up and deliver specimens to DCLS.
- DCLS will immediately forward the second blood specimen to CDC.

- All specimens should be transported at 4°C on cold packs.

VII. Category A/Risk Group 4 (RG4) Kit

Kit Contents:

- 2 - Lavender top plastic blood collection tubes (preserved with EDTA)
- 2 - Biohazard bags w/absorbent material (one for each tube separately)
- 2 - Squares of parafilm to seal plastic blood tubes
- 1 - Secondary containment vessel (black and white)
- 2 - Cold packs (**Freeze prior to shipping**)
- 1 - Ebola Virus Testing Instructions/Fact Sheet
- 1 - Green Clinical Microbiology/Virology Request Form
- 1 - Ziplock plastic bag provided for submission forms and itemized list of contents to be placed outside of the secondary container.
- 1 - Pre-labeled insulated shipper with IATA appropriate labels for Category A shipments.
- 2 - Sheets of blank paper with red diagonal hatch marks (**Required to print Shipper's Declaration Form**).
- 1 - Itemized list of contents card. **Be sure to include quantities (e.g. 5ml EDTA whole blood tube/qty 2).**

NOTE: Please complete the list of contents card and quantities described in the kit contents section above and place this card between the secondary receptacle and outer packaging in accordance with IATA Packing instructions 650.

Please note that these kits may ONLY be used when sending suspect Category A/Risk Group 4 Biological Substances to DCLS. These kits have been pre-labeled with the following labels:

- Green Emergency Viral Testing label for internal DCLS routing
- Category A - Infectious Substance label
- "To" and "From" Address Labels (including blank fields for address, telephone, and responsible person's name).
- Infectious Substance, Affecting Humans Label UN 2814
- 24 Hour DCLS Emergency Contact Label

ALL QUESTIONS AND INQUIRIES REGARDING LABORATORY TESTING SHOULD BE DIRECTED TO THE DCLS CONTACTS LISTED BELOW.

DCLS Emergency Mobile 24/7 Number: 804-335-4617

or

DCLS BT Response Coordinator, Dr. LaToya Griffin-Thomas: 804-385-8057

REFERENCES:

1. DCLS website (Hot Topics Link):
<http://www.dgs.state.va.us/DivisionofConsolidatedLaboratoryServices/HotTopics/tabid/1531/Default.aspx>
2. CDC's New Guidance for US Clinical Labs:
<http://www.cdc.gov/vhf/ebola/hcp/safe-specimen-management.html>
3. CDC's Interim Guidance for Specimen Collection, Transport, Testing and Submission for Persons Under

Investigation for Ebola Virus Disease in the United States:

<http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>

4. OSHA 29 CFR 1910.1030:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS
5. CDC Interim Guidance for Environment Infection Control in Hospitals for Ebola Virus:
<http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>
6. Interim Laboratory Guidelines for Handling/Testing Specimens from Cases or Suspected Cases of Hemorrhagic Fever Virus (HFV), September 10, 2014 (2nd version):
<https://www.asm.org/images/PSAB/Ebola9-10-14.pdf>
7. Fisher Scientific. BD Vacutainer Plastic Blood Collection Tubes K₂EDTA (02-689-03):
http://www.fishersci.com/ecom/servlet/fsproductdetail?storeId=10652&productId=1327530&catalogId=29104&matchedCatNo=0268903&fromSearch=1&searchKey=689||02||03&highlightProductsItemsFlag=Y&endecaSearchQuery=%23store%3DScientific%23nav%3D0%23rpp%3D25%23offset%3D0%23keyWord%3D02-689-03%23searchType%3DPROD%23SWKeyList%3D%5B%5D&xrefPartType=From&savings=0.0&xrefEvent=1413490635752_0&searchType=PROD&hasPromo=0